

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

INTERNATIONAL BROTHERHOOD OF
ELECTRICAL WORKERS LOCAL 595
HEALTH AND WELFARE FUND, on
behalf of itself and all others similarly
situated,

Plaintiffs,

vs.

GLAXOSMITHKLINE LLC, TEVA
PHARMACEUTICAL INDUSTRIES
LTD., and TEVA PHARMACEUTICALS
USA, INC.,

Defendants.

Civil Action No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff International Brotherhood of Electrical Workers Local 595 Health and Welfare Fund (“Plaintiff”), on behalf of itself and all others similarly situated, alleges as follows for its Class Action Complaint against defendants GlaxoSmithKline LLC (“Glaxo”), Teva Pharmaceutical Industries Ltd. (“Teva Ltd.”), and Teva’s subsidiary, Teva Pharmaceuticals USA, Inc. (“Teva USA”) (collectively with Teva Ltd., “Teva”) (collectively with Teva Ltd. and Glaxo, “Defendants”).

I. INTRODUCTION

1. This case is brought on behalf of Plaintiff and the Class (further defined below) – individuals and entities who indirectly purchased, paid for, or reimbursed for

Lamictal®-brand lamotrigine tablets (“Lamictal Tablets”) from Glaxo and/or a generic version of Lamictal Tablets from Teva, other than for resale, in California.

2. As set forth below, Defendants entered into an agreement to refrain from competing with each other in the market for Lamictal Tablets and generic lamotrigine tablets for a period of time. Defendants disguised this anticompetitive agreement as a patent litigation settlement agreement. Defendants obtained a substantial financial benefit from this agreement at the expense of Plaintiff, the beneficiaries of its health fund, and the rest of the Class, who for years were forced to pay inflated, supra-competitive prices for Lamictal Tablets and its generic equivalent.

3. Since 1994, Glaxo has manufactured, marketed, and sold Lamictal Tablets for the treatment of medical conditions such as epilepsy, other seizure disorders, and bipolar disorder, as well as several off-label uses. Lamictal was a highly successful and profitable drug. For the year ending in March of 2008, Glaxo’s sales of Lamictal Tablets in the United States exceeded \$2 billion. Glaxo also markets Lamictal® chewable tablets (“Lamictal Chewables”), which are in most cases lower-dosage chewable lamotrigine tablets, and which had annual domestic sales of about \$50 million during the same time period.

4. Glaxo claimed the exclusive right to sell drugs such as the Lamictal Tablets and Lamictal Chewables based on U.S. Patent No. 4,602,017 (the “’017 patent”). The ‘017 patent expired on July 22, 2008.

5. In 1984, Congress passed the Hatch-Waxman Act, which amended the Federal Food, Drug and Cosmetics Act of 1938, 21 U.S.C. §§ 301-392, to expedite the approval of generic versions of brand-name drugs. Such expedited approval benefits consumers of drugs and entities such as Plaintiff that are responsible for paying for such drugs because generics can offer an effective, cheaper alternative to their brand-name equivalents.

6. Seeking to take advantage of the expedited Hatch-Waxman procedures, in 2002, Teva, the largest generic pharmaceutical company in both the United States and the world, filed Abbreviated New Drug Applications (“ANDAs”) with the United States Food and Drug Administration (the “FDA”) to obtain approval to market generic versions of both Lamictal Tablets and Lamictal Chewables. ANDAs are an abbreviated form of the much more extensive New Drug Applications a pharmaceutical company must file before selling a drug. An ANDA relies on the FDA’s prior determinations of safety and efficacy in connection with the application for the brand-name drug.

7. As required by the Hatch-Waxman Act, Teva’s ANDAs were accompanied by a certification (in this case a so-called “paragraph IV” certification) which represented that the ANDA products did not infringe any valid or enforceable patent(s) pertaining to Lamictal Tablets or Lamictal Chewables, including the ‘017 Patent.

8. As the first ANDA paragraph IV filer, Teva stood to gain the exclusive right to sell generic versions of Lamictal Tablets and Chewables for 180 days, during which time the FDA could not give final approval to any other manufacturer's competing generic ANDA-based drugs. This exclusivity period would grant Teva a highly profitable competitive advantage because, during this period, Teva could garner huge sales volumes and also charge higher prices than subsequent generic entrants (while still charging significantly less than Glaxo's price for the brand-name drug). Furthermore, those generics granted the 180-day exclusivity period obtain a "first mover advantage" and are often able to retain a larger market share than generics that are not allowed to enter the market until later.

9. In 2002, Glaxo sued Teva over both Lamictal Tablets and Chewables, alleging willful infringement of the '017 patent (the "Patent Litigation"). The Patent Litigation triggered a regulatory 30-month stay during which time the FDA was prohibited from granting final approval to Teva's ANDAs unless a district court earlier determined that Glaxo's patent was invalid, unenforceable, or not infringed by Teva's planned generics.

10. The Patent Litigation proceeded to a five-day bench trial in January of 2005. On the final day of trial, the Patent Litigation court issued a bench ruling that invalidated the independent claim of the '017 patent. It also informed the parties that a ruling on the validity of the remaining three claims (which were all dependent claims) would be issued shortly.

11. Faced with the likelihood that its first effort to delay entry of generic versions of Lamictal would fail, Glaxo sought another vehicle to create delay and preserve its lucrative monopoly for as long as possible. With those goals in mind, in February 2005, it entered into purported settlement negotiations with Teva.

12. On or about February 16, 2005, Glaxo and Teva entered into an anti-competitive Settlement Agreement and License and Supply Agreement (collectively, the “Agreements”). In the Agreements, Glaxo offered a variety of financial inducements to Teva in exchange for Teva’s agreement to settle the Patent Litigation in a way that preserved the validity of the ‘017 patent and delayed Teva’s launch of its generic version of the Lamictal Tablets.

13. Under the Agreements, Teva agreed to delay launching its generic version of Glaxo’s Lamictal Tablets until as late as July 22, 2008, which was the expiration date of the ‘017 patent. In effect, the Agreement ignored the fact that Teva had already prevailed on its claim to invalidate the primary claim of the ‘017 patent.

14. In exchange for delaying bringing its generic equivalent to market to compete with Lamictal Tablets, Teva received the right to sell a limited quantity of a generic version of Lamictal Chewables starting on June 1, 2005. As set forth above, the market for Lamictal Chewables was much smaller than the market for Lamictal Tablets.

15. Of greater benefit to Teva, by preserving the ‘017 patent, Teva and Glaxo ensured that Teva would be able to take full advantage of its 180-day exclusivity

period as the first ANDA paragraph IV filer. The Patent Litigation court's ruling on the validity of the primary claim of the '017 patent was a mixed blessing for Teva. At the time of the court's ruling, the FDA had not yet approved Teva's ANDAs for its generic versions of Lamictal. If the court were to issue its final ruling before such approval was obtained, Teva's 180-day exclusivity period would begin to run even though Teva would not be able to launch its generics. Other generic firms could then file their own ANDA applications and enter the market for generic versions of Lamictal at or around the same time that Teva did. This would deprive Teva of millions of dollars of potential profits during what would otherwise be its 180-day exclusivity period and deprive Teva of the "first mover" advantage, the benefits of which can extend indefinitely even beyond that exclusivity period.

16. Therefore, by and through the Agreements, Glaxo and Teva guaranteed themselves supra-competitive revenues for several months, which resulted in anti-competitive overcharges paid by indirect purchasers of Lamictal Tablets such as Plaintiff and its beneficiaries. In the absence of the Agreements: (1) Teva would have brought its generic version of Lamictal Tablets to the market three years earlier, either because it prevailed in the Patent Litigation or chose to launch its generics "at risk"; and (2) other generic manufacturers would have entered the market earlier, causing lower prices for generic Lamictal once Teva's 180-day exclusivity period would have expired.

17. In substance, the Agreements constitute what is known as a “reverse payment agreement”: Teva received financial inducements from Glaxo in exchange for dropping its challenge to Glaxo’s patents and agreeing to delay entry of its generic version of Lamictal Tablets. As the Third Circuit recently noted in *In re K-Dur Antitrust Litigation*, 686 F.3d 197, 216 (3rd Cir. 2012), “reverse payments permit the sharing of monopoly rents between would-be competitors without any assurance that the underlying patent is valid.” Such reverse payment agreements harm consumers and health care payors like Plaintiff because they prevent the steep price reduction in drug prices caused by market entry of generic versions of a brand-name drug subject to the agreement.

18. The Agreements are themselves *prima facie* evidence of an unreasonable restraint of trade. There was no purpose for the financial inducements offered to Teva through the Agreements other than to delay entry of its generic version of Lamictal Tablets and no pro-competitive benefit from the Agreements.

19. Plaintiff, and all others similarly situated, were injured and sustained damages in the form of overcharges, supra-competitive prices, and higher co-payments for branded and generic forms of Lamictal Tablets as a direct and proximate result of Glaxo and Teva’s unlawful Agreements.

II. JURISDICTION AND VENUE

20. This Court has jurisdiction over this action pursuant to: (a) 28 U.S.C. § 1331 because this action arises under the laws of the United States; (b) 28 U.S.C.

§ 1367 because the state law claims asserted in this Complaint are so related to the federal claims in this Complaint so as to be part of a single case or controversy; and (c) 28 U.S.C. § 1337(a) because this is a civil action arising under an Act of Congress protecting trade and commerce against restraints and monopolies.

21. Defendants are found or transact business in this district. Venue is therefore appropriate in this district under 15 U.S.C. § 22 and 28 U.S.C. §1391(b) (1) and (c). Furthermore, a substantial part of the events and omissions giving rise to the claims in this Complaint occurred in this district within the meaning of 28 U.S.C. § 1391(b) (2) because the Patent Litigation from which the Agreements arose was venued in this district. Finally, Defendants have consented in the Agreements to the jurisdiction and venue of this Court.

III. THE PARTIES

22. Plaintiff International Brotherhood of Electrical Workers Local 595 Health and Welfare Fund (“IBEW 595 Fund”) is an “employee welfare benefit plan” and “employee benefit plan” pursuant to the Labor Management Relations Act, 29 U.S.C. § 186(c)(5), and the Employee Retirement Income Security Act, 29 U.S.C. §1001, *et seq.* The IBEW 595 Fund provides health and welfare benefits to current, former and retired IBEW 595 union members and their dependents and beneficiaries. The IBEW 595 Fund is administered from Pleasanton, California.

23. Several beneficiaries of the IBEW 595 Fund have purchased Lamictal Tablets and their generic equivalent during the relevant time period. The IBEW 595 Fund has in whole or in part paid for or reimbursed such beneficiaries' purchases.

24. The IBEW 595 Fund and its beneficiaries have been injured by having paid more for Lamictal Tablets and their generic equivalent than they would have absent Defendants' anticompetitive conduct.

25. Defendant GlaxoSmithKline LLC, fka SmithKline Beecham Corp., is a limited liability company organized under the laws of Delaware with its headquarters at One Franklin Plaza, Philadelphia, Pennsylvania 19101. Glaxo is in the business, among other things, of developing, manufacturing, distributing, advertising, and selling the Lamictal products throughout the United States.

26. Defendant Teva Ltd. is a corporation organized and existing under the laws of the country of Israel with its registered office at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131, Israel. Teva Ltd. is the parent company of Teva USA.

27. Defendant Teva USA is incorporated under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania. Teva USA develops, manufactures, and sells generic pharmaceutical products in the United States. Teva USA is a subsidiary of Teva Ltd.

28. Teva Ltd. manufactures the generic lamotrigine tablet product that Teva USA began selling in the United States in July of 2008.

IV. CLASS ACTION ALLEGATIONS

29. Plaintiff brings this action for itself and, under Rule 23(b)(2) and (b)(3) of the Federal Rules of Civil Procedure, as representative of a class defined as:

All persons or who indirectly purchased Lamictal Tablets from Glaxo or who indirectly purchased a generic version of Lamictal Tablets from Teva – produced, manufactured, marketed, sold, or purchased in the state of California – at any time during the Class Period of August 30, 2006 through January 2009. Excluded from the Class are Defendants and their officers, directors, management and employees, predecessors, subsidiaries and affiliates, and all federal governmental entities.

30. The Class is so numerous that joinder is impracticable. While the exact number of Class members is unknown to Plaintiff, it is believed to be at least in the thousands. Furthermore, the Class is readily identifiable from information and records in possession of the Defendants.

31. Plaintiff's claims are typical of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct by the Defendants – i.e., they paid artificially inflated and supra-competitive prices or higher co-payments for Lamictal Tablets and Teva's generic equivalent and were deprived of the benefits of competition from cheaper generic versions of Lamictal Tablets as a result of Defendants' anti-competitive conduct.

32. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

33. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust and consumer litigation.

34. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members. Defendants have also acted on grounds generally applicable to the entire Class.

35. Questions of law and fact common to the Class include:

- a. whether the conduct alleged herein constitutes a violation of the federal antitrust laws;
- b. whether the conduct alleged herein constitutes a violation of the California antitrust and unfair competition laws;
- c. whether a relevant market needs to be defined in this case and, if so, the definition of the relevant market and whether Glaxo had monopoly power in the relevant market;
- d. whether Defendants' actions illegally maintained Glaxo's or Defendants' monopoly power in the relevant market;
- e. whether Defendants' actions constituted an unlawful and anti-competitive agreement in restraint of trade;
- f. whether, and to what extent, Defendants' conduct caused antitrust injury to indirect purchasers and, if so, the appropriate measure of damages;

- g. whether Defendants fraudulently concealed the terms of their Agreements;
- h. whether Defendants were unjustly enriched by their wrongful conduct; and
- i. whether and to what extent Defendants should disgorge profits with which they were unjustly enriched.

36. Class action treatment is a superior method for the fair and efficient adjudication of this controversy, in that, among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might be impracticable to pursue individually, substantially outweigh any difficulties if any that may arise in management of this class action.

37. Plaintiff is unaware of any difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

V. BACKGROUND

A. The FDA Drug Approval Process and the Hatch-Waxman Act

38. Under the Federal Food, Drug and Cosmetics Act of 1938, 21 U.S.C. §§ 301-392, a company must obtain FDA approval before it may market a prescription

drug. The FDA approval process begins with the submission of a New Drug Application (“NDA”), which must include detailed information about the drug, including information to establish its safety and efficacy and any patents relating to the drug.

39. The FDA publishes the patent information submitted in the NDAs in a publication entitled *Approved Drug Products With Therapeutic Equivalent Evaluations*, widely known as the “*Orange Book*.”

40. In 1984, to facilitate generic competition for brand-name drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585. The stated purpose of the Hatch-Waxman Act was “to make available more low cost generic drugs.” H.R. Rep. No. 98-857(I) at 14-15, reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48.

41. The Hatch-Waxman Act amended the Federal Food, Drug, and Cosmetics Act to allow a company seeking to manufacture a generic version of a patented drug to file an abbreviated version of an NDA, the ANDA, which relies on the FDA’s prior determinations of safety and efficacy made in connection with the application for an already-approved brand-name drug, provided that the applicant demonstrates that its proposed generic is therapeutically and pharmaceutically equivalent to the brand-name drug. Where a generic drug is a complete bio-equivalent to a brand-name drug, the FDA assigns the generic drug an “AB” rating.

42. The ANDA must contain a certification that the proposed generic drug does not infringe any patent listed with the FDA as covering the patented drug. 21 U.S.C. § 355(j)(2)(A)(vii). The applicant may satisfy this requirement by, among other things, certifying that “such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.” *Id.* § 355(j)(2)(A)(vii)(IV). This form of certification is known as a “paragraph IV certification.”

43. When the applicant makes a paragraph IV certification, it must provide written notice to potential affected patent holders, as listed in the Orange Book. 21 U.S.C. § 355(j)(2)(B)(iii)(I). The paragraph IV certification constitutes an artificial act of patent infringement and entitles the patent holder to file an immediate lawsuit for infringement. 35 U.S.C. § 271(e)(2)(A). The patent holder may file such a lawsuit within forty-five days after receiving the certification and, if it does so, the approval of the ANDA is stayed until the earlier of: (a) thirty months having elapsed from receipt of the certification; or (b) the district court entering a judgment, settlement order, or consent decree reflecting a decision or agreement that the patent is invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iii).

44. To encourage generic applicants to challenge suspect drug patents rather than waiting for them to expire, the Hatch-Waxman Act grants the first generic manufacturer who submits a complete ANDA with a paragraph IV certification a 180-day exclusivity period during which no subsequent ANDA applications can become

effective. 21 U.S.C. § 355(j)(5)(B)(iv). This 180-day exclusivity period begins to run when either the first ANDA applicant enters the market with its generic equivalent or a court enters a final judgment that the patent or patents subject to the paragraph IV certification is invalid or not infringed. 21 C.F.R. § 314.107(c)(1).

B. The Economic Significance of Entry of a Generic Drug

45. The introduction of a generic drug into the market has dramatic economic consequences for the brand-name manufacturer and purchasers because generics are significantly lower-priced equivalents of brand-name drugs. “[G]eneric prices can be as much as 90 percent less than brand prices.” FTC Staff Study, *Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (FTC, January 2010), at p.1 (“*FTC Pay-For-Delay Report*”).

46. Because of this lower price, the manufacturer of the brand-name drug will typically suffer a substantial decline in its market share immediately upon entry of a generic equivalent into the market. For example, Glaxo reported in its Form 20-F filings with the United States Securities and Exchange Commission that generic competition had caused a decline in Lamictal sales by 68% in 2008 and 2009.

47. Entry into the market of competing generics for the same brand-name drug causes even further price reductions.

48. Use of generic drugs is encouraged by state law and health plan requirements. Under state generic substitution laws, such as California Business and Professions Code § 4073, and under the terms of most health plans, a pharmacist can

or must substitute an AB generic version of a prescribed brand-name drug when available unless the prescribing physician expressly prohibits such substitution.

49. Furthermore, health plan beneficiaries directly benefit from the availability of generics because health plans typically require substantially lower co-payments for generic drugs as compared to brand-name drugs.

C. Reverse Payment Agreements

50. The economics of the drug industry when combined with the regulatory regime of the Hatch-Waxman Act create the opportunity and incentive for the patent holder / brand-name manufacturer and first ANDA paragraph IV filer to collude at the expense of other potential generic manufacturers and more importantly, health care consumers and payors.

51. The brand-name manufacturer faced with a patent challenge from a generic firm's paragraph IV certification runs the risk that pursuing infringement litigation to a conclusion will result in a determination that its patent is invalid or that the generic (and those that follow after the 180-day exclusivity period) does not infringe any of the patents covering its branded drug.

52. On the other hand, the brand-name manufacturer has little to gain from litigation. It is unlikely to recover damages because the requirement to file an infringement suit within 45 days of receipt of the paragraph IV certification means the generic will not have even entered the market by the time the suit is filed. And although an unfavorable judgment as to patent validity will prevent the brand-name

firm from excluding any future challenger, a favorable judgment will not preclude other would-be entrants from again challenging the patent.

53. Thus, the brand-name manufacturer is best served by settling the patent litigation in a way that maintains the status quo for as long as possible. One simple yet anticompetitive way to do this is to enter into a reverse payment agreement by which the brand-name manufacturer pays off the potential generic manufacturer – either through cash or other financial inducements – to withdraw its patent challenge and delay its entry into the market. The likelihood of this strategy succeeding depends less on the strength of the underlying patent than on the brand-name manufacturer’s ability and incentive to pay off the generic challenger.

54. The ultimate cost of such agreements is borne not by the brand-name manufacturer (which would not enter into such an agreement unless the payment was less than the expected additional profit from delayed entry by the generic) but by consumers and health care payors, who are denied access for several months to significantly lower-priced generic drugs that are the equivalent of brand-name drugs. In the *FTC Pay-For-Delay Report*, the FTC estimated that such reverse payment agreements cost consumers \$3.5 billion per year in increased drug prices.

55. Based on its concern about the anticompetitive effect of such agreements, Congress amended the Hatch-Waxman Act in 2003 to require patent litigation settlements entered into between brand-name and generic drug

manufacturers to be submitted to the Federal Trade Commission and Department of Justice for antitrust review. 21 U.S.C. § 355(j).

VI. FACTUAL ALLEGATIONS

A. Glaxo's Lamictal Products and Patents

54. Glaxo sells Lamictal Tablets pursuant to New Drug Application No. 20-241, which was approved by the FDA in 1994. Glaxo sells Lamictal Chewables pursuant to New Drug Application No. 20-764, which was approved by the FDA in August of 1998. For the 12 months ending March of 2008, Glaxo's sales of Lamictal Tablets in the United States exceeded \$2 billion. The lower-dosage Lamictal Chewable product had annual domestic sales of about \$50 million during the same time period.

55. Upon receiving FDA approval of its NDA for Lamictal Tablets on December 27, 1994, Glaxo was awarded a five-year new chemical entity ("NCE") exclusivity, which expired on or about December 27, 1999. During this five-year period, ANDAs could not be given final approval by the FDA, meaning Glaxo's Lamictal Tablets would be free from generic competition for at least a five-year period.

56. Subsequently, Glaxo received approval for a new label indication for the adjunctive treatment of Lennox-Gastaut syndrome in pediatric and adult populations. As part of that approval, Lamictal Tablets were awarded a seven-year orphan drug exclusivity ("ODE"), commencing on August 24, 1998. Congress enacted the Orphan

Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1982), to encourage firms to develop pharmaceuticals to treat rare diseases and conditions. The Orphan Drug Act establishes a seven-year ODE period during which no ANDA for the same use of a generic version of the drug can be approved. 21 U.S.C. §360cc. However, ODE is indication-specific, meaning that the FDA can approve an ANDA for non-ODE protected uses during the seven-year period. The ODE for Lamictal Tablets expired on or about August 24, 2005, although Lamictal Tablets were approved for additional non-ODE protected indications, which allowed for ANDAs to be approved prior to this date.

57. The '017 patent, which expired on July 22, 2008, was the only patent listed in the Orange Book for Lamictal Tablets. The '017 patent, along with another patent (U.S. Patent No. 5,698,226), was listed in the Orange Book as pertaining to Lamictal Chewables, although the '226 patent played no role in the Patent Litigation between Glaxo and Teva.

58. In 2007, two years *after* execution of the Agreements between Glaxo and Teva, Glaxo received a six-month Pediatric Exclusivity, which did not extend the '017 patent's expiration date but did prevent any ANDA applicant for a product claimed by the '017 patent from receiving final regulatory approval until January 22, 2009, assuming that the '017 patent was not invalidated (a risk eliminated by the Agreements) or there was a showing that a particular ANDA product did not infringe that patent.

B. Teva's ANDA Applications

59. On April 1, 2002, Teva filed ANDA No. 76-388, seeking approval to manufacture and sell AB generic lamotrigine tablets. A short time later, Teva filed ANDA No. 76-420, seeking approval to manufacture and sell generic lamotrigine chewable tables.

60. Teva was the first to file substantially complete ANDAs for AB generic equivalents to Lamictal Tablets and Lamictal Chewables with paragraph IV certifications as to the '017 patent. It also filed a paragraph IV certification to the second patent listed in the Orange Book regarding Lamictal Chewables.

61. Accordingly, Teva could have obtained the potentially valuable 180-day exclusivity period for generic lamotrigine tablets and lamotrigine chewables, during which no other manufacturers could sell generic versions of Lamictal Tablets or Lamictal Chewables (except for Glaxo, which had the legal right to sell authorized generic versions).

62. The FDA granted final approval to Teva's ANDA for lamotrigine chewables on June 21, 2006 and Teva's ANDA for lamotrigine tablets on August 30, 2006.

63. In doing so, the FDA concluded that: (a) Teva's lamotrigine chewables have the same safety and efficacy as, and are AB-rated, to Glaxo's Lamictal Chewables of the same dosage strength; and (b) Teva's lamotrigine tablets have the

same safety and efficacy as, and are AB-rated to, Glaxo's Lamictal Tablets of the same dosage strength.

C. The Patent Litigation

64. In 2002, soon after Glaxo's receipt of Teva's paragraph IV certifications to the '017 patent, Glaxo filed Civil Action No. 02-3779 and Civil Action No. 02-4537 (again the "Patent Litigation") against Teva in the United States District Court for the District of New Jersey, alleging that Teva's two ANDAs infringed the '017 Patent. Glaxo did not file suit against Teva based upon the second patent listed for Lamictal Chewables.

65. Both suits were filed within 45 days of receipt of the Paragraph IV notices from Teva, entitling Glaxo to automatic 30-month stays of approval of both of Teva's ANDAs.

66. Following discovery, the Patent Litigation proceeded to a bench trial from January 18 to January 25, 2005. By this time, the 30-month stays of regulatory approval on both of Teva's ANDAs had either expired or were about to expire.

67. On the final day of trial, the Patent Litigation court orally ruled that claim 1 (the independent claim) of the '017 patent was invalid. It also indicated that a ruling on the validity of the three remaining claims (dependent claims) would be issued.

68. This ruling raised concerns: (1) for Glaxo, that generic entry was imminent for the highly lucrative Lamictal Tablets and Lamictal Chewables; and (2) for Teva, that the ruling could lead to the triggering of its 180-day exclusivity

period for its generic version of Lamictal Tablets before Teva had received final FDA approval, as set forth below.

69. Specifically with respect to Teva, despite what would appear to be a favorable outcome, the probable timing of the court's expected ruling posed a problem for Teva. The entry of a final court decision invalidating the '017 patent would start the clock on Teva's 180-day exclusivity period for that patent regardless of whether Teva actually had an FDA-approved product to sell during that period. The invalidation of the '017 patent would also open the floodgates of competition for competition among generic manufacturers of Lamictal Tablets and Lamictal Chewables because, after Teva invalidated the '017 patent, other generics would be able to start selling their AB-rate versions once they too received FDA final approval.

70. Furthermore, if the '017 patent were invalid, the six-month Pediatric Exclusivity period could not attach to the end of that patent and thus would not be an effective barrier to entry to Teva or the other generic manufacturers that filed ANDAs to sell generic versions of either Lamictal Tablets or Chewables.

71. If a final decision in the Patent Litigation could have been delayed past August 30, 2006 (the date Teva received final approval from FDA for its generic lamotrigine tablets), then Teva could have entered the market "at-risk." This would have allowed Teva to take full advantage of its 180-day exclusivity period.

72. The final decision in the Patent Litigation being delayed until after August 30, 2006 was unlikely, however, because the Patent Litigation court provided

an oral ruling on the first '017 Patent claim in January 2005, and indicated that rulings on the patent's other claims would be forthcoming shortly thereafter.

73. In summary, the possibility that Teva might have succeeded in invalidating all of the '017 patent claims posed competitive risks to both Glaxo and Teva. Glaxo faced the danger that, if the Patent Litigation court invalidated all the '017 patent's claims, it would suffer a severe reduction in future revenue due to the loss of exclusivity of Lamictal Tablets and Lamictal Chewables years prior to the expiration of the '017 Patent. Teva faced the risk that it might achieve that result prior to final FDA approval for its ANDAs, which would likely start Teva's 180 days of exclusivity for its generic lamotrigine tablets and chewables and deprive Teva of the benefit of its 180-day exclusivity period.

74. Indeed, Teva's ANDA application for generic lamotrigine chewables did not receive final approval until June 21, 2006 and its ANDA application for generic lamotrigine tablets did not receive Final Approval until August 30, 2006. Therefore, if the January 2005 bench trial resulted in a successful invalidation of the '017 patent before December 2005, Teva's 180-day exclusivity would have been triggered by the court's final decision and expire for both the generic lamotrigine tablets and generic lamotrigine chewables before Teva could even begin to bring those products to market. Other competitors that had obtained final approval of their ANDAs for generic versions of Lamictal Tablets or Lamictal Chewables as of June 2006

(assuming invalidation of the '017 patent's claims in the Patent Litigation) could then enter the market before (or at the same time) as Teva.

75. In other words, both Glaxo and Teva had an interest in delaying the entry of Teva's generic versions of Lamictal Tables and Lamictal Chewables. Glaxo had an interest in delaying Teva's entry (and all other generic manufactures' entry) for as long as possible so that Glaxo could continue to earn monopoly and anti-competitive profits on Lamictal Tablets. Teva had an interest in preventing and/or delaying a successful court decision until it would be in a position to take advantage of its valuable 180-day exclusivity for generic lamotrigine tablets.

D. The Anti-Competitive Reverse Payment Agreements

76. In recognition of the risks faced by Defendants and the mutual advantage from delay, the parties immediately started settlement negotiations, and on February 2, 2005, Defendants had a conference with the Patent Litigation court during which they asked the court to refrain from ruling on the validity of the remaining '017 Patent claims.

77. Approximately two weeks following that conference, Glaxo and Teva entered into the Agreements, which taken as a whole were a reverse-payment agreement that amounted to a combination and conspiracy to restrain trade.

78. The Agreements are set forth in a Settlement Agreement between Glaxo and Teva USA and a License & Supply Agreement between Glaxo and Teva Ltd. (again, the "Agreements"), both of which are dated February 16, 2005. The

Settlement Agreement expressly provides that both the Settlement Agreement and the License & Supply Agreement are part of the consideration that Glaxo offered Teva “in reaching agreement to settle.”

79. The Agreements permitted Teva to sell limited amounts of generic lamotrigine chewables in the United States, starting on June 1, 2005. Teva was supplied by Glaxo with chewable lamotrigine product which Teva began selling as an authorized generic on May 25, 2005.

80. Under the Agreements, Glaxo also granted Teva: (a) a royalty-free, non-transferable license under the ‘017 patent to import, manufacture, have manufactured and have sold Teva’s generic version of Lamictal Tablets in the United States starting on July 21, 2008, at 5:00 p.m. Pacific time, which was when the ‘017 patent expired; and (b) a waiver of any potential future pediatric exclusivity applicable to Teva’s generic version of Lamictal Tablets (which did not exist in February 2005).

81. Even though Teva had already succeeded in invalidating the ‘017 patent’s primary, independent claim, and even though there was therefore a significant risk that the patent’s other, dependent claims might be invalidated, the settlement gave little or no discount or reduction to the patent’s exclusionary power (*i.e.*, it did not give Teva the right to enter the market with its generic version of Lamictal Tablets prior to the patent’s expiration).

82. And even though Teva’s generic versions of both Lamictal Tablets and Lamictal Chewables were subject to the exact same patent claims and thus, Teva’s

chances of litigation success were the exact same for both products, Teva was allowed to start selling a generic version of the smaller-market, \$50 million a year chewable product within three months after the settlement while it agreed to wait at least three years to start selling a generic version of the more than \$2 billion a year tablet product.

83. The differing treatment and entry dates that Glaxo and Teva negotiated for Lamictal Tablets and Lamictal Chewables (both of which were subject to the exact same patent claims and litigation risks) reflect the reality: (a) that Defendants did not choose (nor did they attempt to choose) entry dates for the two products that reasonably reflected the probability that all of the asserted claims of the '017 patent were invalid; and (b) that Defendants were not concerned about whether the agreement would keep Teva off the market for the larger-market product longer than was warranted by the patent.

84. Instead, this differing treatment reflects the reality that Teva was paid financial compensation as part of an anti-competitive agreement to delay entry of its generic Lamictal Tablets and to put the "cork in the bottle" to deny the FDA authority to approve other ANDAs for Lamictal Tablets.

85. Because Teva's generic versions of Lamictal Chewables were AB-rated only to branded Lamictal Chewables and were not AB-rated to Lamictal Tablets, Teva could not, prior to July 2008, provide lower-priced generic substitutes for Lamictal Tablets that would: (1) be broadly substituted for the higher-priced Lamictal Tablets,

or (2) otherwise efficiently compete with Lamictal Tablets. Accordingly, the indirect purchaser, third party payor and end-user benefits gained by the early generic lamotrigine chewable entry date of June 2005 are small in comparison to the indirect purchaser, third party payor, and end-user harm caused by the anti-competitive delayed lamotrigine tablet generic entry date of July 2008.

86. Teva received significant consideration, incentives, and benefits in exchange for its agreement to: (a) abandon its efforts to invalidate the '017 patent; and (b) forego competing against Glaxo's Lamictal Tablets with a less-expensive generic version until the '017 patent expired. First, Teva was permitted to enter the United States market within a few months with an authorized generic version of the much smaller market, \$50 million per year Lamictal Chewables.

87. In the pleadings from subsequent litigation between Teva and Glaxo, Glaxo admitted that its agreement allowing Teva to enter the market in three months with a generic version of the smaller-market Lamictal Chewable product "formed part of the bargain between Glaxo and Teva" and was one of the "benefits" that Teva received for agreeing to abandon its efforts to invalidate the '017 patent and to stay off the market with the larger-market lamotrigine tablet product for at least three years.

88. The second consideration and incentive that Teva received for: (a) dropping its efforts to invalidate the '017 patent; and (b) foregoing competition against Glaxo with a generic lamotrigine tablet until the '017 patent expired was an illegal, anti-competitive agreement in which Teva would be virtually guaranteed the

right to use all or most of its 180-day exclusivity periods for both lamotrigine tablets and lamotrigine chewables, which would enable it to charge higher prices during those periods, and also maximize its longer-term profits by obtaining the “first mover advantage.” Glaxo was also benefitted because the Agreements delayed not only the entry of Teva’s generic version, but other generics as well.

89. Thus, by and through these Agreements, Teva and Glaxo afforded themselves a guarantee of higher revenues during these periods of time which resulted in anti-competitive overcharges being thrust upon consumers.

90. On April 4, 2005, Teva and Glaxo drafted and filed a Stipulation and Order of Dismissal in the Patent Litigation seeking the dismissal of all claims and counterclaims. On the same day the court signed the dismissal, it also entered an order withdrawing the bench ruling that invalidated claim 1 of the ‘017 patent.

E. The Launch of Teva’s Generic Lamotrigine Tablets

91. Even though it received FDA approval to launch lamotrigine tablets almost two years earlier, Teva delayed launching its generic version of Lamictal Tablets until on or about 5:00 p.m. Pacific time on July 21, 2008, the earliest date permitted under the Agreements.

92. Because of Teva’s 180-day exclusivity on generic versions of Lamictal Tablets, which was secured by and through the anti-competitive Agreements, no other generic was allowed to launch, and none, in fact, did launch, prior to January 22, 2009.

93. Teva's 180-day exclusivity period for its generic version of Lamictal Tablets would have been triggered earlier if: (a) Teva and Glaxo had settled the Patent Litigation without the provision of illegal financial inducements to Teva from Glaxo, which would have resulted in a settlement that provided for an earlier entry of Teva's less expensive generic version of Lamictal Tablets; and/or (b) Teva had launched its generic lamotrigine tablets (as it would have) upon receipt of final FDA approval on August 30, 2006, either "at-risk" or after successfully invalidating the '017 patent.

94. Instead, because of the unlawful Agreements, Teva did not enter the market until July 21, 2008, leaving its 180-day exclusivity in place and thereby blocking final FDA approval and entry of other generic versions of Lamictal Tablets until January 2009.

95. The Agreements between Glaxo and Teva that delayed Teva's launch of the generic lamotrigine tablets and guaranteed Teva's 180-day exclusivity period were not necessary for the settlement of the Patent Litigation and constituted an ancillary restraint of trade.

F. Defendants' Anti-Competitive Agreements Enabled Them to Charge Supra-Competitive Prices for Both Branded and Generic Lamotrigine Tablets

96. The Agreements between Teva and Glaxo guaranteed that Glaxo would have exclusivity on the lucrative Lamictal Tablet product with no generic competition for more than three years from the date of the Agreements, approximately two years after Teva received final FDA approval for its lamotrigine tablets.

97. This exclusivity and accompanying supra-competitive pricing generated many millions of dollars of additional revenue for Glaxo during this period at the expense of indirect purchasers who would have otherwise paid or reimbursed lower prices or co-payments for generic lamotrigine tablets. In addition, higher, anti-competitive and supra-competitive prices for Lamictal Tablets paid by direct purchasers were passed-on and borne substantially by indirect purchasers.

98. In consideration for Teva's delaying its launch of its generic version of the blockbuster Lamictal Tablet until close of business on July 21, 2008, Teva secured: (1) the right to immediately launch a generic equivalent of the Lamictal Chewable product, which generated some limited profit for Teva, but created much smaller consumer savings and benefits than an earlier launch of the lucrative lamotrigine tablet product (i.e., the indirect purchaser benefits generated by the earlier launch of generic lamotrigine chewables pales in comparison to the consumer harm created by the anti-competitive delay in entry of the generic lamotrigine tablets); and (2) a virtual guarantee of its ability to sell its generic version of Lamictal Tablets during the 180-day exclusivity period.

99. Teva's generic market exclusivity and accompanying supra-competitive pricing generated many millions of dollars of additional revenue for Teva during the six-month exclusivity period at the expense of indirect purchasers who would have otherwise paid or reimbursed lower prices or co-payments for generic lamotrigine tablets. In addition, higher, anti-competitive and supra-competitive prices for Teva's

generic lamotrigine tablets paid by direct purchasers were passed-on and borne substantially by indirect purchasers.

100. Defendants' unlawful conduct thus delayed not only the launch of less-expensive generic versions of Lamictal Tablets for the benefit of indirect purchasers, but allowed both Teva and Glaxo to profit from charging anti-competitive and supra-competitive prices for lamotrigine tablets in the relevant market.

VII. FRAUDULENT CONCEALMENT AND EQUITABLE TOLLING

101. Defendants have engaged in deceptive, misleading, and fraudulent efforts to conceal the true nature of their unlawful conduct from Plaintiff and the Class through misrepresentations, omissions, and partial disclosures omitting material facts, as described below.

102. Glaxo and Teva agreed amongst themselves, and contractually bound one another, to withhold from public disclosure material facts concerning the Agreements. In the Licensing Agreement, Article I, Section 1.1, Glaxo and Teva agreed that the terms of their agreements contained in the Licensing Agreement and Settlement Agreement, among any other agreements among them concerning Lamictal and its generic equivalents, would be deemed "Confidential Information."

103. As "Confidential Information," the Licensing Agreement forbade Glaxo and Teva from disclosing the details of their Agreements to the public, including Plaintiff and the Class.

104. Glaxo and Teva further agreed, and bound themselves, in Section 6.3 of the Licensing Agreement, to not make any “public announcement” or engage in any “[p]ublicity” concerning the Agreements.

105. The anti-publicity provision set forth Section 6.3 of the Licensing Agreement permitted Teva to issue a brief press release concerning Defendants’ agreements, which press release was attached as an exhibit to the Licensing Agreement. That press release was issued by Teva from Jerusalem, Israel on February 17, 2005. Aside from disclosing that parties had reached agreements resulting in estimated launch dates for generic lamotrigine pursuant to licenses, the press release told the public that: “Additional terms of the settlement agreement were not disclosed.”

106. Upon information and belief, Glaxo has not issued any press releases disclosing the terms of the Agreements.

107. Upon information and belief, upon informing the Patent Litigation court of their settlement in February 2005, neither Glaxo nor Teva filed with the district court copies of the Settlement Agreement or Licensing Agreement. If such Agreements were provided to the district court, they were not filed in a manner that was available to the public, Plaintiff, or the Class.

108. The proposed Stipulation and Order of Dismissal drafted by the Glaxo and Teva for presentation to the Patent Litigation court in February 2005, and attached as an exhibit to their Settlement Agreement, did not attach the Agreements nor

completely disclose those Agreements' material terms. Concerning the terms of those Agreements, the proposed Stipulation and Order of Dismissal revealed only that: "Plaintiff and Defendant have reached an agreement to settle the Litigation, which is set forth in this Stipulated Order, a separate Settlement Agreement and a separate License and Supply Agreement, each of which is being executed contemporaneously."

109. While it is Teva's routine practice to publicly announce when it receives final FDA approval to market or sell generic equivalents in the United States, it made no public statement that the FDA granted final approval for its ANDA for lamotrigine tablets (25mg, 100 mg, 150 mg, and 200 mg) on August 30, 2006. Upon information and belief, Teva did not inform the public of this FDA final approval because it had agreed with Glaxo to maintain Glaxo's monopoly and anti-competitive pricing for Lamictal Tablets until July 2008.

110. Since entering into the Agreements in February 2005, Glaxo and Teva have each made multiple filings with the United States Securities and Exchange Commission (the "SEC"), including annual reports issued on Form 20-F. Material terms of the Agreements were omitted and withheld from those filings with the SEC.

111. In its 2005 Form 20-F filed with SEC on or about March 20, 2006, Teva briefly discussed the Agreements, omitting disclosure of material facts concerning the anti-competitive nature of the Agreements and other material facts (including but not limited to the Patent Litigation court's ruling that the first claim of Glaxo's '017 patent was unenforceable and not infringed by Teva's ANDA). Teva's disclosure

concerning the challenged agreements in its 2005 Form 20-F was limited to the following statement:

In February 2005, as settlement of a patent dispute with GlaxoSmithKline (“GSK”) over the generic version of Lamictal®, GSK granted Teva an exclusive royalty-bearing license to distribute generic lamotrigine chewable tablets (5 mg and 25 mg) in the United States no later than June 2005. GSK also granted Teva the exclusive right to manufacture and sell its own generic version of lamotrigine tablets (25 mg, 100 mg, 150 mg and 200 mg) in the U.S., with an expected launch in 2008 prior to patent expiry in July 2008 (plus six months of expected pediatric exclusivity).

112. In accordance with their agreement to withhold public knowledge concerning material terms of the Agreements, neither the Licensing Agreement nor Settlement Agreement were provided as exhibits to this Teva Form 20-F, or any subsequently-filed Form 20-F.

113. No details concerning Defendants’ Agreements were contained in Teva’s 2006 Form 20-F.

114. Teva’s Forms 20-F filed with SEC for years 2007 and 2008 contained substantially similar statements and material omissions as contained in the 2005 Form 20-F concerning the Agreements.

115. On July 22, 2008, Teva issued a press release from Jerusalem, Israel, and filed with the SEC on Form 6-K, a statement that disclosed only generalized and partial details of its Agreements with Glaxo and containing material omissions. Concerning the Agreements, Teva’s press release disclosed only that: “In February 2005, GlaxoSmithKline and Teva entered into an agreement to settle patent litigation

under which GlaxoSmithKline granted Teva the exclusive right to manufacture and sell a generic version of Lamictal® during the six-month pediatric exclusivity which ends on January 22, 2009.”

116. It its 2005 Form 20-F filed with SEC on or about March 3, 2006, Glaxo likewise omitted substantive disclosure of the terms of the Agreements and other material facts (including but not limited to the Patent Litigation’s court’s ruling that the first claim of Glaxo’s ‘017 patent was unenforceable and not infringed by Teva’s ANDA). Glaxo’s disclosure concerning the challenged Agreements in its 2005 Form 20-F was limited to the following statements:

Lamictal. The patent on lamotrigine is not due to expire until 2009 (USA). Litigation challenging the validity of this patent in the USA has been settled. In Europe, the corresponding patent has expired and generic competition exists.
[Footnotes omitted.]

* * *

Lamictal

In August 2002, the Group commenced an action in the US District Court for the District of New Jersey against Teva Pharmaceuticals USA Inc., alleging infringement of the Group’s compound patent for lamotrigine, the active ingredient in Lamictal oral tablets. That patent affords protection through January 2009 after giving effect to a grant of paediatric exclusivity by the FDA. Teva had filed an ANDA with the FDA with a certification of invalidity of the Group’s patent. The parties reached a settlement agreement pursuant to which the Group has granted Teva an exclusive royalty-bearing license to distribute in the USA a generic version of lamotrigine chewable tablets. In addition, Teva was granted the exclusive right to manufacture and sell Teva’s own generic version of lamotrigine tablets in the USA with an expected launch date in 2008.

117. In accordance with their agreement to withhold public knowledge concerning material terms of the Agreements, neither the Licensing Agreement nor Settlement Agreement were provided as exhibits to this Glaxo Form 20-F, or any subsequently-filed Form 20-F.

118. Glaxo's Form 20-F filed with SEC for year 2006 contained substantially similar statements and material omissions concerning the facts and Agreements, challenged as unlawful in this action. The Form 20-F filed by Glaxo for 2007 contained even fewer disclosures concerning the Agreements and subsequent Forms 20-F did not contain any disclosures.

119. A September 25, 2006 press release issued by Glaxo in the United States announced a new FDA-approved indication for Lamictal, but was entirely devoid of any disclosure concerning the Agreements.

120. An October 15, 2007 press release issued by Glaxo in the United States announced research findings concerning extended-release Lamictal, but was entirely devoid of any disclosure concerning the Agreements.

121. A June 1, 2009 press release issued by Glaxo in the United States announced FDA approval of Lamictal XRTM, but was entirely devoid of any disclosure concerning the Agreements.

122. As a result and proximate cause of Defendants' concealment, Plaintiff learned of the existence of their claims against Defendants shortly prior to becoming

parties in this action. For the same reasons, Class members were likely to be reasonably unaware of Defendants' unlawful acts and the claims alleged in this action.

123. A reasonably diligent indirect purchaser, including Plaintiff and members of the Class, could not have learned of their claims alleged in this action, or all the material events giving rise to their claims in this action, prior to various press reports and public accounts concerning the filing of the lawsuit by the direct purchasers on or about February 17, 2012.

124. Plaintiff and the Class' lack of knowledge as to the existence of their claims against Defendants and was not due to any fault or lack of reasonable diligence on their part, but rather due entirely or substantially to the acts of Defendants designed to conceal and hide the true nature of their unlawful and inequitable conduct. To the contrary, Plaintiff has been diligent in bringing its claims in this action, both individually and on behalf of the Class.

125. Plaintiff and the Class' claims alleged in this action were tolled, equitably and/or as a result of Defendants' fraudulent concealment, at least until February 17, 2012.

VIII. THE RELEVANT MARKET

126. The Agreements are themselves *prima facie* evidence of an unreasonable restraint of trade.

127. Furthermore, direct proof exists that Glaxo had monopoly power over the price of lamotrigine tablets and their AB-rated generic equivalents. Such direct

evidence will include: (1) manufacturers' and/or market-wide transactional data that will show a significant, non-transitory decline in lamotrigine tablet prices upon entry of generic lamotrigine tablets that had not occurred until generic entry, and (2) abnormally high price-cost margins enjoyed by Glaxo prior to the entry of generic competition. This direct evidence of monopoly power obviates the need to define a relevant product market in determining whether Glaxo had monopoly power.

128. Assuming that a relevant market needs to be defined, the relevant product market is all lamotrigine tablet products – i.e., Lamictal Tablets (as defined above) and AB-rated equivalent lamotrigine products. The relevant geographic market is the United States and its territories. A firm that was the only seller of such products in the United States could and would impose a significant, non-transitory price increase without losing sufficient sales to render the price increase unprofitable, as demonstrated by Glaxo's ability to profitably charge supra-competitive prices during the period in which it lacked generic competition. There are no reasonably interchangeable drug products that were during the relevant time period available to prescribing physicians for the indications for which lamotrigine products are prescribed.

129. Through the anti-competitive conduct alleged herein, Defendants were able to profitably charge anti-competitive and supra-competitive prices for lamotrigine tablets without losing substantial sales, and thus, by definition, maintained monopoly power with respect to lamotrigine tablets sold in the United States. Those anti-

competitive and supra-competitive prices were passed-on and borne by indirect purchasers, in the form of higher prices and co-payments.

130. Glaxo's market share of the relevant market was 100% until the entry of Teva's generic version of the Lamictal Table. Glaxo and Teva's combined market share of the relevant market was 100% from that point until the expiration of Teva's 180-day exclusivity period.

131. At all relevant times, Glaxo and later Glaxo in combination with Teva benefited from high barriers to entry with respect to this relevant market due to patent and regulatory protections.

FIRST CAUSE OF ACTION

DECLARATORY JUDGMENT ACT CLAIM CONCERNING VIOLATIONS OF SECTION 1 OF THE SHERMAN ACT (15 U.S.C. §1)

132. Plaintiff incorporates and realleges all paragraphs in this Complaint, as though fully set forth below.

133. Beginning in or about January 2005, Glaxo and Teva engaged in a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to: (a) fix the price at which Plaintiff and the members of the Class would pay for lamotrigine tablets at the higher, branded price until July 21, 2008 by preventing the sale of Teva's generic lamotrigine tables in the United States until July 21, 2008; and (b) fix the price at which Plaintiff and the members of the Class would pay for Teva's generic lamotrigine tables from July 21,

2008 until January 22, 2009 by preventing the sale of generic versions of lamotrigine tablets other than Teva's in the United States until January 22, 2009.

134. By entering into these unlawful conspiracies, Defendants unlawfully conspired in restraint of trade and committed a violation of Section 1 of the Sherman Act, 15 U.S.C. §1. Defendants' Agreements are price fixing agreements between actual or potential competitors and, thus, are *per se* violations of Section 1. In the alternative, Defendants' Agreements are unreasonable restraints of trade in violation of Section 1 when viewed under a "quick look" or "rule of reason" mode of analysis.

135. Plaintiff and all members of the Class have been injured in their business and property by reason of Defendants' unlawful contract, combination and conspiracy. During the Class Period, Plaintiff and the members of the Class paid more for their purchases of Lamictal Tablets and/or Teva's generic lamotrigine tablets than they would have paid absent Defendants' illegal conduct, and/or were prevented from substituting a cheaper generic alternative for their purchases of the more expensive Lamictal Tablets and/or Teva's generic equivalent.

136. Defendants' actions, as alleged herein, constitute violations of Section 1 of the Sherman Act, 15 U.S.C. §1. Pursuant to the Declaratory Judgment Act, Plaintiff seeks a judgment and decree that Defendants have violated Section 1 of the Sherman Act.

SECOND CAUSE OF ACTION

DECLARATORY JUDGMENT ACT CLAIM CONCERNING VIOLATION OF SECTION 2 OF THE SHERMAN ACT FOR

**MONPOLIZATION AND ATTEMPTS TO MONOPOLIZE
(15 U.S.C. §2)**

137. Plaintiff incorporates and realleges all paragraphs in this Complaint, as though fully set forth below.

138. As a result of the unlawful Agreements and the combinations, conspiracies, acts, practices and conduct in furtherance of enforcing and complying with the Agreements, Glaxo unlawfully restrained and monopolized trade and attempted to monopolize trade with specific intent in violation of Section 2 of the Sherman Act. Glaxo did, in fact, monopolize trade in the United States in the market for lamotrigine tablets and eliminated competition in the sale of Lamictal Tablets and generic equivalents in the United States during the Class Period.

139. As a result of the unlawful Agreements and Defendants' combinations, acts, practices and conduct in furtherance of enforcing and complying with the Agreements, Glaxo and Teva conspired to restrain and monopolize trade in the United States in the market for Lamictal Tablets and eliminated competition to the sale of Lamictal Tablets and generic equivalents in the United States, thereby preserving Glaxo's monopoly in the market for Lamictal Tablets for Defendants' mutual financial gain.

140. Plaintiff and all members of the Class have been injured in their business and property by reason of Defendants' efforts to restrain and monopolize such trade. During the Class Period, Plaintiff and the members of the Class paid more for their purchases of Lamictal Tablets and/or Teva's generic lamotrigine tablets than they

would have paid absent Defendants' illegal conduct, and/or were prevented from substituting a cheaper generic alternative for their purchases of the more expensive Lamictal Tablets and/or Teva's generic equivalent.

141. Defendants' actions, as alleged herein, constitute violations of Section 2 of the Sherman Act, 15 U.S.C. §2. Pursuant to the Declaratory Judgment Act, Plaintiff seeks a judgment and decree that Defendants have violated Section 2 of the Sherman Act.

THIRD CAUSE OF ACTION
TREBLE DAMAGES CLAIM FOR VIOLATION OF THE
CARTWRIGHT ACT
(CALIFORNIA BUSINESS AND PROFESSIONS CODE § 16700 *ET SEQ.*)

142. Plaintiff incorporates and realleges all paragraphs in this Complaint, as though fully set forth below.

143. The Agreements and Defendants' combinations, acts, practices and conduct in furtherance of enforcing and complying with the Agreements violated California's Cartwright Act, California Business and Professions Code §§ 16700 *et seq.*, which prohibits, among other things, any combination to create or carry out restrictions in trade or commerce and any agreement to fix the price of a product.

144. Plaintiff and the members of the Class have been injured in their business or property by reason of Defendants' violations of the Cartwright Act. During the Class Period, Plaintiff and the members of the Class paid more for their purchases of Lamictal Tablets and/or Teva's generic lamotrigine tablets than they would have paid

absent Defendants' illegal conduct, and/or were prevented from substituting a cheaper generic alternative for their purchases of the more expensive Lamictal Tablets and/or Teva's generic equivalent.

145. Pursuant to California Business and Professions Code § 16750, Plaintiff and the members of the Class are entitled to three times the damages sustained by them as a result of Defendants' violations of the Cartwright Act.

FOURTH CAUSE OF ACTION
RESTITUTION FOR VIOLATION OF CALIFORNIA'S UNFAIR
COMPETITION LAW
(CALIFORNIA BUSINESS AND PROFESSIONS CODE § 17200 *ET SEQ.*)

146. Plaintiff incorporates and realleges all paragraphs in this Complaint, as though fully set forth below.

147. The Agreements and Defendants' combinations, acts, practices and conduct in furtherance of enforcing and complying with the Agreements violated California's Unfair Competition Law, California Business and Professions Code §§ 17200 *et seq.*, which prohibits any unlawful, unfair or fraudulent business act or practice.

148. Plaintiff and the members of the Class have been injured in fact and lost money by reason of Defendants' violations of the Unfair Competition Law. During the Class Period, Plaintiff and the members of the Class paid more for their purchases of Lamictal Tablets and/or Teva's generic lamotrigine tablets than they would have paid absent Defendants' illegal conduct, and/or were prevented from substituting a

cheaper generic alternative for their purchases of the more expensive Lamictal Tablets and/or Teva's generic equivalent.

149. Pursuant to California Business and Professions Code § 1704, Plaintiff and the members of the Class are entitled to equitable relief, including restitution of the amounts they have lost and Defendants have gained as a result of their violations of the Unfair Competition Law.

FIFTH CAUSE OF ACTION

UNJUST ENRICHMENT UNDER CALIFORNIA LAW

150. Plaintiff incorporates and realleges all paragraphs in this Complaint, as though fully set forth below.

151. Defendants received substantial benefits from Plaintiff and members of the Class in the form of supra-competitive prices for Glaxo's Lamictal Tablets and Teva's generic lamotrigine tablets during the Class Period.

152. In light of the illegality of the Agreements and Defendants' combinations, acts, practices and conduct in furtherance of enforcing and complying with the Agreements, it would be unjust for Defendants to retain these benefits at the expense of Plaintiff and members of the Class.

153. Under California's law of unjust enrichment, Plaintiff and the members of the Class are entitled to disgorgement of these benefits from Defendants and restitution of these benefits to Plaintiff and the members of the Class.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the proposed Class, prays for judgment against all Defendants, jointly and severally, as follows:

1. That the Court declare, adjudge, and decree that the Defendants and each of them have violated Sections 1 and 2 of the Sherman Antitrust Act, California Business and Professions Code §§ 16700 *et seq.* and 17200 *et seq.* and that Plaintiff and others similarly situated are entitled to relief under the doctrine of unjust enrichment;

2. That Plaintiff and all others similarly situated be awarded treble damages permitted by California Business and Professions Code § 16750 suffered by reason of Defendants' violations of California Business and Professions Code § 16700;

3. That Plaintiff and all others similarly situated be awarded equitable relief including restitution permitted by California Business and Professions Code § 17204 arising from Defendants' violations of California Business and Professions Code § 17200;

4. That Plaintiff and all others similarly situated be awarded equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment under California law;

5. That the Plaintiff and Class be awarded reasonable attorneys' fees and costs; and

6. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of all claims and complaints in this Complaint so triable.

DATED: October 25, 2012

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